U.S. Food and Drug Administration

Safety

Antipsychotic drugs: Class Labeling Change - Treatment During Pregnancy and Potential Risk to Newborns

including Haldol, FazaClo, Fanapt, Clozaril, Risperdal, Zyprexa, Seroquel, Abilify, Geodon, Invega, Loxitane, Moban, Navane, Orap, Saphris, Stelazine, Thorazine, Symbyax

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AUDIENCE: Psychiatry, OBGYN

ISSUE: FDA notified healthcare professionals that the Pregnancy section of drug labels for the entire class of antipsychotic drugs has been updated. The new drug labels now contain more and consistent information about the potential risk for abnormal muscle movements (extrapyramidal signs or EPS) and withdrawal symptoms in newborns whose mothers were treated with these drugs during the third trimester of pregnancy.

The symptoms of EPS and withdrawal in newborns may include agitation, abnormally increased or decreased muscle tone, tremor, sleepiness, severe difficulty breathing, and difficulty in feeding. In some newborns, the symptoms subside within hours or days and do not require specific treatment; other newborns may require longer hospital stays.

BACKGROUND: Antipsychotic drugs are used to treat symptoms of psychiatric disorders such as schizophrenia and bipolar disorder.

RECOMMENDATION: Healthcare professionals should be aware of the effects of antipsychotic medications on newborns when the medications are used during pregnancy. Patients should not stop taking these medications if they become pregnant without talking to their healthcare professional, as abruptly stopping antipsychotic medications can cause significant complications for treatment.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/22/2011 - Drug Safety Communication [3] - FDA]

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm
2. /Safety/MedWatch/HowToReport/DownloadForms/default.htm
3. /Drugs/DrugSafety/ucm243903.htm